

Remarks:

The Official Action mailed July 9, 2007 has been carefully considered. Reconsideration and allowance of the subject application, as amended, are respectfully requested.

Status of the Claims

Claims 48-50, 52-57, 59 and 60 are pending in the present application. Claims 1-47, 50, 51, 58, 61-98 have been cancelled. Claim 48 has been amended. Claims 99 through 114 have been added.

Amendments to the Specification

The specification has been amended to recite that: "The present application is a divisional of U.S. patent application serial number 10/037,902, filed on November 9, 2001, now U.S. patent number 6,699,218, which claims priority to provisional U.S. patent application serial number 60/247,598, filed on Nov. 9, 2000, which is assigned to the assignee of the present application and incorporated herein by reference."

In adding this cross-reference to the parent application, Applicants note that the reference is being added to the specification after the time period required by 37 CFR 1.78(a)(2)(ii). Applicants also note that in the comments on final rule changes set forth in Official Gazette of January 22, 2002 the Office indicated that it would not require a petition pursuant to 37 CFR 1.78(a)(3) in such circumstances:

If an applicant includes a claim to the benefit of a prior-filed nonprovisional application or international application designating the United States elsewhere in the application but not in the manner specified in 1.78(a)(2)(i) and (iii) (e.g., if the claim is included in an unexecuted oath or declaration or the application transmittal letter) within the time period set forth in 1.78(a)(2)(ii), the Office will not require a petition (and the surcharge under 1.17(t)) to correct the claim if the information concerning the claim contained elsewhere in the application was recognized by the Office as shown by its inclusion on a filing receipt. This is because the application will have been scheduled for publication on the basis of the information concerning the claim contained elsewhere in the application within the time period set forth in 1.78(a)(2)(ii). Of course, the applicant must still submit the claim in the manner specified in 1.78(a)(2)(i) and (iii) (i.e., by an amendment in the first sentence of the specification or in an

application data sheet) to have a proper claim under 35 U.S.C. 120 and 1.78 to the benefit of a prior-filed application.” *1254 OG 121 (January 22, 2002)*.

Applicants note that this claim was recognized by the Office as reflected in the attached printout from PAIR and reflected on the coversheet of the published application. As such, even though the addition of the cross-reference to the parent application is being filed after the time period required by 37 CFR 1.78(a)(2)(ii), a petition pursuant to 37 CFR 1.78(a)(3) is not required since the claim to the benefit of the parent application has been recognized by the Patent Office.

Amendments to the Claims

Claim 48 has been amended to recite: “a flexible subcutaneous infusion cannula.” Support for this amendment may be found in now cancelled claim 50. No new matter has been entered by this amendment.

Claim 48 has also been amended to recite: “a rigid or semi-rigid skin penetrating member movably positioned within the infusion cannula between a retracted position wherein a sharpened tip of the penetrating member is contained within the housing.” Support for this amendment may be found in paragraph [0019] of the present application which recites that the “transcutaneous infusion set that utilizes a rigid or semi-rigid penetrating member to place a soft cannula through the skin of the patient.” No new matter has been entered by this amendment.

Claims 99 through 114 have been newly added. Support for these claims may be found through out the specification, claims as originally filed and, for example, in **FIGS. 19** though **21**. No new matter has been entered by this amendment.

Rejections Under 35 USC §103(a)

Claims 48-50, 52-57, 59-60 stand rejected under 35 USC §103(a) as being unpatentable over Gross et al., U.S. Patent No. 5,997,501, in view of Douglas et al., U.S. Patent No. 6,685,674. Furthermore, claims 48-50, 52-57, 59-60 stand rejected under 35 USC § 103(a) as being unpatentable over Gross, alone.

As an initial matter, upon review of the present application, it appears that Douglas does not qualify as prior art to the present application. More specifically, Douglas et al., was filed on

March 4, 2002. The Douglas patent claims the benefit of U.S. Provisional Application No. 60/273,490, filed on Mar. 4, 2001 as well as U.S. Provisional Application No. 60/299,842, filed on Jun. 19, 2001. However, the present application, filed on October 8, 2003 is a division of U.S. Patent Application No. 10/037,902, filed on Nov. 9, 2001, now U.S. Patent 6,699,218, which claims the benefit of U.S. Provisional No. 60/247,598, filed on Nov. 9, 2000. Accordingly, the present application claims the benefit of an earlier effective filing date of Nov. 9, 2000, whereas the Douglas patent claims the benefit of Mar. 4, 2001 and Jun. 19, 2001. Therefore, the Applicants respectfully assert that Douglas does not constitute prior art to the present application.

In addition to the above, Gross et al., fails to anticipate or render obvious the presently claimed invention. In particular, Gross not only fails to disclose the skin penetrating member movably positioned within the infusion cannula, as recognized in the *Office Action* of July 9, 2007 on page 4, but also fails to disclose the cannula itself as well as the skin penetrating member being contained entirely within the housing when the skin penetrating member is in the retracted position.

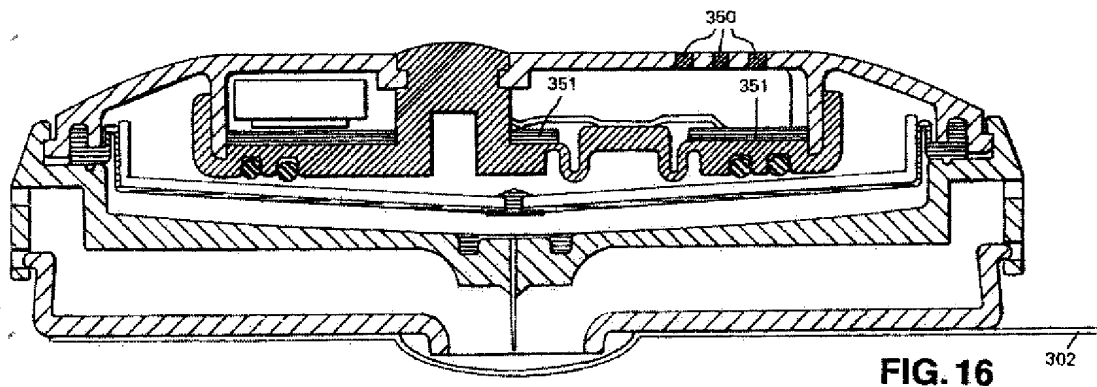
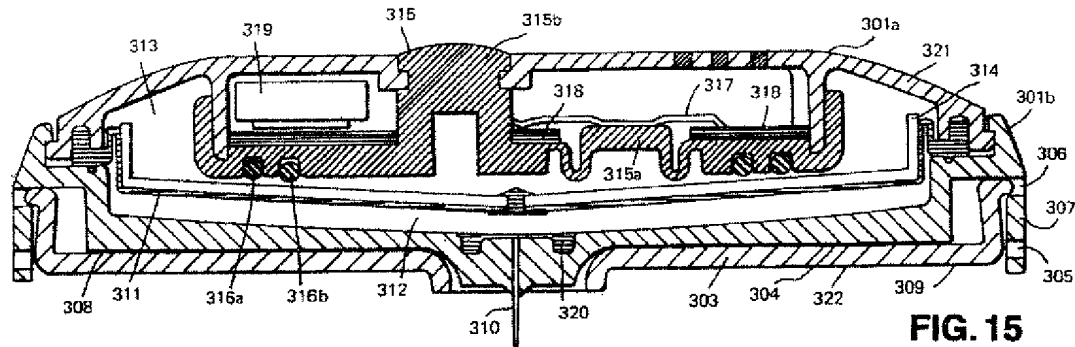
To support the obviousness rejection, the *Office Action* asserts that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have the skin penetrating member movably positioned within the infusion cannula, since it has been held that rearranging parts of an invention involves only routine skill in the art.” *Office Action* of July 9, 2007, page 7. However, as noted above, Gross does not disclose all of the presently claimed subject matter, i.e., Gross does not disclose a rigid or semi-rigid skin penetrating member movably positioned within a flexible infusion cannula between a retracted position wherein a sharpened tip of the penetrating member is contained within the housing and an extended position wherein the sharpened tip of the penetrating member extends from the distal tip of the cannula. Rather, Gross only discloses a needle 14 (Col. 10, lines 27-41). Accordingly, this is not a rearranging of parts, as not all of the presently claimed parts are present in Gross.

In addition, the *Office Action* asserts that “it has been held that constructing a formally integral structure in various elements involves only routine skill in the art. The device of Gross has all the operational elements as claimed but simply has the skin penetration element passing

through conduit **308/309**.” *Office Action* of July 9, 2007, page 7. However, the device of Gross does not have all of the operational elements as claimed.

More specifically, Applicants note that the presently claimed transcutaneous infusion set “utilizes a rigid or semi-rigid penetrating member to place a soft cannula through the skin of the patient” and that “[t]he penetrating member is then removable from the soft cannula to provide better patient comfort by avoiding a sharpened rigid or semi-rigid tip from residing in the patient’s subcutaneous tissue.” Paragraph [0019] of the present application. Thus, the combination of the cannula and skin penetrating member are “more than constructing a formally integral structure in various elements” as noted in the *Office Action*, but rather, as stated in the specification, the flexible cannula provides better patient comfort. Gross does not suggest providing a flexible cannula to provide better patient comfort or provide guidance as to how one might integrate a flexible infusion cannula and a skin penetrating member moveably positioned within the infusion cannula, where in a retracted position the sharpened tip of the penetrating member is contained within the housing. Therefore, Gross does not anticipate or render obvious the claimed subject matter.

Applicants also note that Gross does not disclose that the hollow needle is moveably positioned with respect to the housing. As illustrated in **FIGS. 15 and 16** reproduced below, Gross provides a cover **303** which may be retracted allowing the hollow needle **310** to extend outwardly from the lower surface **322** of the protective displaceable cover **303**. However, the needle **310** is not moveably positioned with respect to the housing **301**, instead the separate cover **303** retracts to expose the needle **310**. It is also noted that in what one might consider to be a retracted position, the sharpened tip of the needle is not contained within the housing **301** itself.



Accordingly, in addition to the reasons asserted above, Gross does not render the presently claimed subject matter obvious as Goss does not disclose or suggest providing a skin penetrating member movably positioned within an infusion cannula. Accordingly, the Applicants respectfully request that the rejection under 35 USC §103 be withdrawn.

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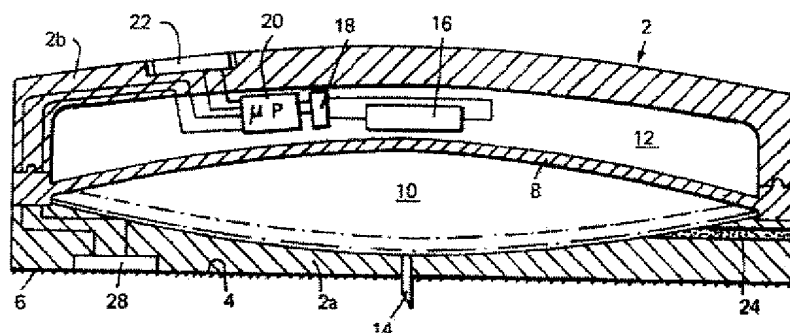
Claims 48-50, 52-57, 59-60 stand rejected under 35 USC §103(a) as being unpatentable over Gross et al., U.S. Patent No. 5,997,501, in view of Larsen et al., U.S. Patent No. 5,968,011.

As noted above, Gross et al., fails to teach or render obvious the presently claimed subject matter. In addition, the modification of Gross with Larsen would render Gross

More specifically, as taught by Larsen and illustrated in FIG. 7 reproduced below, an insertion needle 14 extends through the housing from the top surface of the housing to the bottom surface of the housing and through the cannula 13 extending from the housing.



Providing the insertion needle of Larsen in Gross (illustrated in **FIG. 3** reproduced below) would puncture the membrane **8** rendering the dispensing device of Gross inoperable as the insertion needle would pass through a portion of the membrane **8** to access the needle **14**. In addition, Applicants note that Gross provides a separate syringe insertion plug **24** avoiding insertion of a needle through a portion of membrane **8**. Thus, it would appear that the combination of the references would not have been obvious because it would render Gross inoperable and unsatisfactory for its intended purpose. See MPEP §2143.01(V).



Furthermore, the combination of Gross and Larsen fail to disclose or render obvious all of the claimed elements. More specifically, Gross in view of Larsen fail to teach a skin penetrating member is contained entirely within the housing when the skin penetrating member is in the retracted position. As noted above, Gross fails to teach a skin penetrating member contained within a housing, rather (referring back to **FIGS. 15** and **16** reproduced above,) the needle **310** of Gross projects from the bottom of the housing **301** and the cover **303** is displaceable around the needle **310**.

Larsen fails to address the deficiencies of Gross. As may be appreciated, when the insertion needle **14** of Larsen is removed from the infusion set, the needle is not contained entirely within the housing. Rather, a portion of the needle remains above and outside of the infusion set, until the needle is completely removed and is no longer associated or contained by the infusion set, as illustrated in **FIG. 11**.

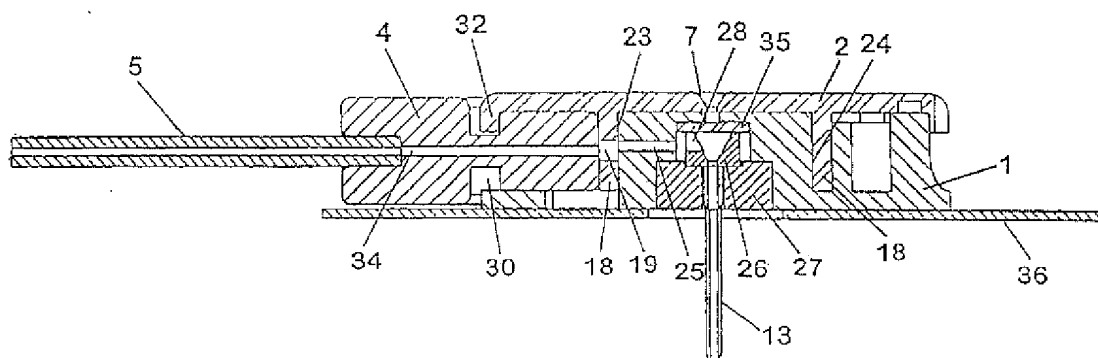


FIG. 11

Accordingly, the combination of Gross and Larsen fail to teach a skin penetrating member contained within the housing when the skin penetrating member is in the retracted position. Therefore, Applicants respectfully submit that the rejection under 35 USC §103 be withdrawn.

Having dealt with all the objections raised by the Examiner, it is respectfully submitted that the present application, as amended, is in condition for allowance. Thus, early allowance is earnestly solicited.

If the Examiner desires personal contact for further disposition of this case, the Examiner is invited to call the undersigned Attorney at 603.668.6560.

In the event there are any fees due, please charge them to our Deposit Account No. 50-2121.

Respectfully submitted,

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